



HTAi RICC Interest Group
Regulatory Interactions & Conditional Coverage

Minutes of Annual Business Meeting,
Friday, 13 May 2016, Keio Plaza Hotel, Tokyo

1 Introduction

This was the first Business Meeting of the Regulatory Interactions and Condition Coverage Interest Group. Approximately 25-30 people attended the meeting which was chaired by Franz Pichler, the transitional chair of the RICC Interest Group. Urs Brügger the transitional vice-chair sent his apologies.

These minutes were prepared by the Chair of the RICC Interest Group.

2 Launch of the RICC Interest Group

The Chair welcomed participants and officially launched the RICC Interest Group explaining that the group is the outcome of the merger of two existing Interest Groups, the HTA-Regulatory IG and the Conditional Coverage/ Access with Evidence Development IG.

The Chair explained that the merger came about due to the realisation of significant and growing overlap between the two IGs and that the concept was first proposed by Sean Tunis (then Chair of the Conditional Coverage/AED IG) during the 2015 Oslo HTAi conference, when the two IGs were co-hosting a pre-meeting workshop on Adaptive Pathways.

The Chair covered the process by which the two IGs had merged and the decision to officially launch during the HTAi annual conference in Tokyo.

2.1 Terms of Reference

It was noted that specific Terms of Reference (ToR) are required for the Interest Group and that in the interim, temporary ToR had been drafted for approval by the members during the business meeting. Following discussion and approval or amendment of the proposed ToR, a formal ToR would be developed and circulated to members.

As part of the development of the ToR, the participants of the meeting were asked to address each of the following:

Objectives of the Interest Group

To create added value for interested HTAi members through networking, information exchange, idea generation and collaborative work on special projects leading to conference presentations or publications.

- The participants agreed with the proposed objectives

Focus

The RICC IG focuses on the changing dynamics around evidence development that are leading to greater interaction with regulatory stakeholders as well as the increasing interest in mechanisms that involve conditionality of access relating specific to evidentiary development.

- The participants agreed with the proposed Focus

Scope

In relation to geographies and technologies

- All geographies – but focused on those with relevant ongoing/developing activities
- All new technologies – initial focus on pharmaceuticals and devices

In relation to issues

- Adaptive pathways
- Risk sharing / Managed entry agreements (focus on the outcomes-based processes such as PBRsAs, CED, CTC)
- Post-marketing additional data collection
- HTA-Regulatory Interactions relating to evidence development (parallel reviews etc)
- Early dialogue / scientific advice (relating to the above)

Out of Scope

In relation to geographies and technologies

- Technologies – established technologies

In relation to issues

- Disinvestment (to avoid overlap with Disinvestment IG)
 - Purely financial based Risk Sharing Agreements
 - HTA-Regulatory Interactions relating to sharing of information
- The participants debated about whether the membership of the IG was sufficiently diverse to be able to focus on both pharmaceuticals and devices, or whether the scope should be narrowed to pharmaceuticals, at least in the short term. Several participants with interests in devices argued for maintaining inclusion of devices and so the decision was to maintain devices in scope.

Governance

It was proposed to adapt the RICC ToR to the new overarching ToR being developed by the HTAi IG Steering Committee as follows:

- A chair and vice-chair shall be elected on a three-year basis
- To help ensure continuity, the vice-chair shall succeed the chair
- The election of the vice-chair will occur during the IG's Annual Business Meeting
- The election will be conducted by a member of the HTA Secretariat
- Any member of HTAi may apply, although previous activity in the IG is encouraged

The chair indicated that both he and Urs were transitional chairs until an election could be held and indicated that while an election had been planned for this launch meeting, that the transitory issues faced by the society had meant a delay in the ability to identify and communicate with members until one week out from the conference. Therefore he proposed to defer the election until the next HTAi annual meeting in Rome, 2017. In the interim he asked the participants if they would be happy for him and Urs to be the chair and vice-chair for the period 2016-2017.

- The participants agreed with the proposal for governance, including the adaption of the ToR to align with the HTAi template and also the suggestion to defer the elections to

2017 with Franz and Urs being chair/vice-chair until that time.

- A question was raised about how to enable the participation of regulatory participants and included a suggestion to reach out to the main regulatory society the DIA. The chair observed that the HTAi annual meeting was traditionally held on dates overlapping with the DIA annual meeting (with the Tokyo conference being the only exception in recent years) and that the regulatory community would obviously prioritise their own societies meetings over that of HTAi.

[[addendum – the coming Rome HTAi conference in 2017 will once again overlap with DIA thus reducing opportunities for regulator participation in the HTAi meeting]]

Methods of working

Annual Business Meeting

The key annual event for the IG is the ABM that is held as part of the Annual HTAi Meeting.

Newsletter

The RICC IG will update the membership via an emailed newsletter on a biannual basis. The newsletters will also be archived on the website

Work streams

Members of specific work streams / project groups will organise their communication schedule amongst themselves but will also undertake to provide updates for dissemination via the newsletter.

Ad hoc teleconferences

Considering time zone challenges, calls for the whole membership are generally not an optimal means of communication but may be considered if necessary. The chair noted that the HTAi IG Steering Committee had announced that a WebEx facility for the IGs was planned to become operational shortly following the conference.

- The participants agreed with the proposal for methods of working

3 Current activities of the RICC

The chair presented the current activities and resources of the RICC

3.1 Website

A new HTAi website for the RICC had been developed and was launched the week prior to the Tokyo meeting. The website replaced those of the two previous Interest Groups. Within the website's home page were links to the RICC Repository, RICC Newsletters and other RICC documents and materials. In the interests of transparency, it was proposed that AGM presentations and minutes be included on the website.

As part of the website development a resource has been developed that will contain HTAi-related conference presentations and reports, or other publically available materials that we believe to be of direct relevance to the RICC. Initially this will focus on the RICC produced materials (such as workshops or panels) or materials that RICC members request to be uploaded to the website.

3.2 RICC Repository

The RICC Repository is an adaptation of an existing Regulatory-HTA Interactions IG work stream. Since 2012, the Regulatory-HTA Interactions IG hosted a repository on its website that contained:

- Peer-reviewed papers
- Links to governmental activities relating to regulatory-HTA interactions
- Links to non-governmental activities relating to regulatory-HTA interactions

The primary objective of the RICC Repository is to provide a regularly updated bibliography of peer-reviewed literature on the key topics in scope of the Interest Group, namely:

- Adaptive pathways
- Early dialogue / scientific advice involving both regulators and HTA bodies
- HTA-Regulatory Interactions relating to evidence development
- Managed entry agreements (focussed on outcomes-based agreements)
- Performance-linked Risk Sharing Agreements (PBRsAs)
- Coverage with evidence development (CED)
- Conditional treatment continuation (CTC)
- Post-marketing additional data collection

The RICC Repository is managed by Michelle Mujoomdar (CADTH) and supported by an information specialist David Kaunelis (CADTH). Michelle outlined the search methodology for the peer review literature (which is described in detail on the RICC Repository page) and indicated that an initial retrieval using the RICC search terms from 1 January 2015 to 4 February 2016 had been added to the existing HTA-Regulatory Repository that included peer-reviewed literature from 1999 to October 2015. Michelle indicated that it was her intention to update the Repository on a quarterly basis.

The existing list of governmental and non-governmental regulatory-HTA interactions has been stored on a separate page. The chair indicated that these data are non-systematic and are updated at the interest of members. He also indicated that if members think there is value in such data then it would be possible to continue to update and potentially expand to include conditional coverage (relating to clinical uncertainty).

3.3 Blog on Conditional Coverage

The Conditional Coverage IG had established a blog on their website that was intended to stimulate discussion amongst the IG membership. While a great idea, there was limited posting to the blog and therefore the chair proposed not to take the blog forwards in the RICC at this time.

- The participants agreed with the proposal not to pursue the blog

4 Discussion on new activities of the RICC

The chair introduced the discussion with reflection that the current focus of the RICC should be the annual HTAi meeting and therefore moving towards Rome 2017, he requested ideas for panels so as to meet the needs of the membership. He also introduced some possible new

work streams for the Interest Group.

- The remainder of the meeting consisted of a lively discussion focussed on ideas for panels for Rome 2017.
- One participant emphasized the need for a clear plan or agenda for what the point of the panels would be and what by doing them would the RICC want to achieve.

Panel proposals

Over the course of the discussion, four clear proposals for potential panels that the RICC could support for Rome 2017 emerged. It was noted that panels put forwards by Interest Groups gain an advantage in the panel selection process. Each of the panel proposals below will require a 'champion' from within the RICC membership to lead the development and this will be supported by the chair and vice-chair. Ideally, small working groups from the RICC membership will come together and then help the champion develop the panel and identify speakers.

1) *Recent advances in interactions between regulators and HTAs across the drug lifecycle.*

There was debate as to whether this should be covered in multiple panels (early advice, pre-launch, launch, post-launch) to allow for greater detail or a single overarching panel that covers the whole lifecycle holistically. Pragmatically, Rome 2017 is likely to be oversubscribed and so a single panel would have more chance of being accepted. Alternatively, if more detail was preferred then this could make a nice ½ day pre-conference workshop

2) *The current status of Managed Entry Agreements.* This panel would focus on outcomes-based managed entry agreements for pharmaceuticals. One participant offered to lead this panel and the chair and vice-chair will be following up.

3) *Implications of patient group advocacy for faster approval and access.* There is increasing pressure and proposals for mechanisms from patient groups in relation to both regulatory and HTA processes. Part of this panel could also consider the public health remit of HTAs in relation to patient. This would be proposed as a collaborative panel with the Patient and Citizen Interest Group and would involve multiple stakeholders from outside the HTAi community, namely patient, physician and payers.

4) *Devices.* While a specific panel was not identified, during the discussion the device representatives voiced concern that while the panels were covering pharmaceuticals that there are strong differences in relation to devices, for example in how to generate evidence to satisfy both regulatory and payers. The device representatives considered it valuable to the HTAi community to consider developing a device-focussed panel for the Rome conference. The chair/vice-chair will be following up with these representatives in order to see if a panel idea could be developed and then brought back to the membership for endorsement.

In relation to the outputs of the panels for the benefit of the RICC members and the broader HTAi community, one suggestion was to develop panel summary reports. A second suggestion was to video the panel and then to develop short 3-5 minute youtube clips. In both ways, the discussion of the panel wouldn't be forgotten following meeting.

Work streams

Due to the lengthy panel discussion, there was limited time to discuss potential new work streams. However, the AGM participants did indicate that there was no interest in pursuing development of a glossary of definitions for RICC-related topics.

5 **AOB**

Considering the trend for HTA activities to move 'upstream' and now a similar trend with payers, several participants floated the idea to expand the RICC to payers. This proposal will become a key item for discussion at the next RICC AGM in Rome 2017.

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Prof Urs Brügger, Zurich University of Applied Science (brgu@zhaw.ch), ISG vice-Chair

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